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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,805	03/06/2002	Kunihiko Morizane	029430-497	1558

7590

07/07/2003

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 07/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,805

Applicant(s)

MORIZANE ET AL.

Examiner

Ganapathy Krishnan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Objections

Claims 13 is objected to because of the following informalities: In claim 13 the numeral 3 appears twice to the left of the formula shown. Appropriate correction is required.

Specification

The disclosure is objected to because of the following informalities: At page 25 of the specification the title "CLAIMS" should be replaced with either "What Is Claimed Is" or "We Claim". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 11 recite, "a hydroxyl group substituted with a hydroxyl-protecting group". It is not clear what this means. The term protected hydroxyl group is suggested if applicants intend R3 to be a protected hydroxyl group.

In Claim 3 it is not clear what "methoxyethy". Clarification is needed as to what group is intended.

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In formula (4) of Claim 4, some valence problems arise based on the definition of Y and Z. Y cannot be hydrogen in the formula. If Y is a carbon atom then it is not tetravalent. Z can be hydrogen or alkyl or alkenyl only if Y is nitrogen. If Y were oxygen or sulfur then attachment of Z to either would make it positively charged. A cannot be attached to Z if Z is hydrogen. The recitation as such is very confusing and gives rise to valence problems. The recitation "Z attached to A may form a ring" or vice versa is indefinite. This valence problem is also seen in Claims 5, 11 and 12.

In Claim 5, the recitation "as defined above" is indefinite. In all occurrences, phrases referencing the meaning of a variable as defined in some alternative, preceding location, such as "above", without distinct reference to the particular location of said meaning or definition, renders the claim(s) in which said phrase(s) appear indefinite. The reference to some alternative location for a definition is superfluous if the definition or meaning is already set forth in a claim or said definition or meaning is clearly set forth in an independent claim from which a claim depends. In all occurrences and under these circumstances, the phrases should be deleted from the claims as superfluous.

Claim 12 does not recite what Z is.

In Claims 1, 2, 4, 6, 11 and 13 the terms "an alkyl group(s)", "an alkoxy group(s)" and "a halogen atom(s)" is recited. It is not clear if applicants intend only one said group or more than one.

Claims that are dependent on rejected base claims, which are indefinite, are also rendered indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Awano et al (Arch. Pharm. Pharm. Med. Chem. 1996, 329, 66-72).

Awano et al, drawn to the synthesis of cytidines and uridines, disclose synthetic conversion of uridine derivatives to the corresponding cytidine derivatives (see Scheme 1, page 67, 5a-e to 7a-e) via reaction of the uridines with triethylamine and triisopropylbenzenesulfonyl chloride followed by reaction with 25% ammonium hydroxide (see page 69, right column, conversion of 5a-e into 7a-e).

This disclosure is seen to meet the limitations of claims 1, 6 and 13.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Awano et al (Arch. Pharm. Pharm. Med. Chem. 1996, 329, 66-72) in combination with Karimian (US 5610292).

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7-9 are drawn to a method of producing cytidine derivatives according to claim 1 wherein the tertiary amine used is N-methylpiperidine, N-methylmorpholine, 1,4-diazabicyclo[2.2.2]octane, N,N'-dimethyliperazine or trimethylamine, wherein the said dehydrating reactant is acid halide or acid anhydride and the reaction is carried out in the presence of deacidifying agent, wherein the deacidifying agent is p-toluenesulfonyl chloride.

Awano et al, drawn to the synthesis of cytidines and uridines, disclose synthetic conversion of uridine derivatives to the corresponding cytidine derivatives (se Scheme 1, page 67, 5a-e to 7a-e) via reaction of the uridines with triethylamine and triisopropylbenzenesulfonyl

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chloride followed by reaction with 25% ammonium hydroxide (see page 69, right column, conversion of 5a-e into 7a-e).

A similar conversion is disclosed by Karimian (see col. 3, lines 18-65), wherein the base used can be a C5-C12 heterocyclic amine and trialkylamines the alkyl groups on the amine can be C1-C6 alkyl.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute structurally similar trimethylamine or other heterocyclic amines and also substitute p-toluenesulfonyl chloride in the method as instantly claimed with reasonable expectation of success since these compounds have been shown to be used for the said process.

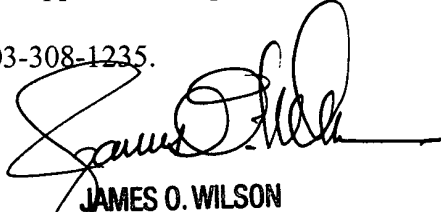
One of ordinary skill in the art would be motivated to do so in order to reduce cost.

Claims 11 and 12 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 703-305-4837. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600